DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-885/S-020

Pfizer Inc.
Attention: Mr. James A. Parker, Jr.
235 42nd Street
New York, NY 10017-5755

Dear Mr. Parker:

Please refer to your supplemental new drug application dated August 8, 2000, received August 9, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accupril (quinapril hydrochloride) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert based on clinical trials and postmarketing reports and provides for final printed labeling revised as follows:

This supplemental application proposes the addition of the following adverse events under **ADVERSE REACTIONS/Hypertension and/or Heart Failure:**

1. Flatulence

2. Urinary tract infection

3. Edema and arthralgia

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your August 8, 2000 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Sandra Birdsong
Regulatory Health Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research